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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.              | CONFIRMATION NO.       |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/734,670   | 12/11/2003  | Richard S. Ginn      | 15997.4002                       | 6280                   |
| 34313 7590 05/18/2010<br>ORRICK, HERRINGTON & SUTCLIFFE, LLP<br>IP PROSECUTION DEPARTMENT<br>4 PARK PLAZA<br>SUITE 1600<br>IRVINE, CA 92614-2558 |             |                      | EXAMINER<br>TYSON, MELANIE RUANO |                        |
|  |             |                      | ART UNIT<br>3773                 | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>05/18/2010          | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/734,670

**Applicant(s)**

GINN, RICHARD S.

**Examiner**

MELANIE TYSON

**Art Unit**

3773

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2010 and 05 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-33, 35-39, 41-45, 47-58, 60-97, 100 and 103-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-33, 35-39, 41-45, 47-58, 60-97, 100 and 103-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/26/10, 5/5/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the applicant's amendment received 26 March 2010. Claims 1-29, 34, 40, 46, 59, 98, 99, 101, and 102 are cancelled. The application is not in condition for allowance for the reasons set forth below. The corrections made to the claims have been accepted.

#### ***Claim Objections***

Claim 94 is objected to because of the following informalities: the second portion of the implantable device has already been defined in the independent claim thus the claim should read --the-- second portion instead of "a" second portion as recited in line 2. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 30-33, 35-39, 41-45, 47-58, 60-97, 100, and 103-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** Claim 30 requires situating the implantable device **within** a first and second piercing. Claims 105 and 106 require releasing the device while located **within** the piercings. This language is confusing and unclear, since claim 30 also requires the device to engage the tissue flaps. It is unclear as to how the device can engage the surfaces of the tissue flaps if positioned within piercings in the tissue flaps.

Appropriate correction is required. Claims 31-33, 35-39, 41-45, 47-58, 60-97, 100, 103, and 104 are also rendered indefinite as depending from indefinite claim 30.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 30-33, 35-39, 41-45, 47-58, 60-97, 100, and 103-106 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 111-210 of copending Application No. 10/856,493 in view of Oman et al. (U.S. Patent No. 7,288,105 B2).**

The claims of the copending application also recite a method of closing a patent foramen ovale by situating a clip through overlapping tissue flaps to close a tunnel therebetween. The co-pending application fails to recite an implantable device as recited in the instant application.

Oman discloses a method for treating a patent foramen ovale (see entire document) comprising the steps of advancing an implantable device (30) through the vasculature of a subject within an elongate delivery apparatus (a catheter; for example, see column 9, lines 25-27) and situating, engaging, and releasing the implantable device within piercings of overlapping first and second tissue flaps defining a tunnel (piercing is formed by the needle-like tips of the filament 40 of the implantable device which penetrate the tissue), wherein a first elongate portion of the device (end of 40 in left atrial chamber) engages the first tissue flap and is exposed in a second (left) atrial chamber, a second elongate portion of the device (end of 40 in left atrial chamber or vice versa - see claim 62) engages the second tissue flap and is exposed in a first (right) atrial chamber, an intermediate portion of the device lies between the first and second portions (see below for details on the composition on the first and second portions in which the intermediate portion lies between the defined boundaries), and the first and second elongate portions may be considered to be made up of a first end (passed through the tissue flap in chambers), intermediate region (portions within the tissue flaps), and second end (a portion of segment within the tunnel formed by the flaps and panel portion 32 or vice versa in which the first portion would comprise a portion lying substantially perpendicular to a longitudinal axis of a portion within the first piercing as recited in claim 42) all pivotally coupled in that the entire portion (40) is formed of a spring material and thus any portion may pivot relative to the other to retain the tissue flaps (for example, see Figure 24 for illustration). Oman further disclose the steps of deploying the biased device from the elongate delivery apparatus such that it

transforms, pivots, or transitions to a retaining configuration (for example, see Figure 24 and column 9, lines 25-31), securing the second portion to the device to retain the second portion against the second tissue flap (for example, see Figure 24), the second portion includes retaining arms or laterally extending members (opposing portions of panel 32 defined by support structure 36) capable of engaging and retaining the second tissue flap as they lie substantially in a plane parallel to the second tissue flap and thus may be considered "locking elements" that lockingly engages the filament ( or wire "suture" 40), the device may comprise NITINOL or other shape memory material (for example, see column 8, lines 20-32), and the first portion (for example, portion 32 of the device) resides substantially flat against the first tissue flap in the retaining configuration (in order to fully contact the tissue; for example, see column 7, lines 39-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the clip in '493 application with the implantable device taught by Oman since the substitution of one known element for another would have yielded predictable results, namely, providing an effective means for closing a patent foramen ovale.

This is a provisional obviousness-type double patenting rejection.

***Allowable Subject Matter***

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest, in combination with other limitations in the claims, the first and second tissue flaps are engaged such that the first flap is held in

contact with the second tissue flap to close the tunnel and the tunnel therebetween is closed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/  
Examiner, Art Unit 3773  
May 14, 2010